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LETTER TO THE EDITOR

Vaccine-related serious adverse events might have been under-recognized in the pivotal HPV vaccine randomized trial

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To the Editor:

After seeing several healthy girls developing a severe chronic illness soon after HPV vaccination [1], I analyzed all HPV vaccine randomized controlled trials.

The overwhelming majority of pre-licensure HPV vaccine randomized trials did not use inert placebo as comparator. The largest nine-valent HPV immunization trial [2] compared the newly developed nine-valent HPV vaccine vs. the four-valent HPV formulation. The innovative nine-valent HPV dose has more than double HPV virus-like particles and aluminum adjuvant than the previous formulation. Double-blind safety analysis contrasted 7071 subjects immunized with the nine-valent vaccine vs. 7078 who had the four-valent dose. The nine-valent cohort had significantly more systemic serious adverse events; $n = 233$ (3.3%) vs. $n = 183$ (2.6%) in the other group. Our calculated 2×2 contingency table p value was 0.0125. Oddly, only two subjects (0%) in each group were judged to have a vaccine-related serious adverse event. The authors did not comment on this incongruity.

This discrepancy arising from a pivotal large randomized double-blind trial suggests that nine-valent HPV vaccine-related serious adverse events were under-recognized. This emerging information casts further doubt on HPV vaccine safety.

Compliance with ethical standards

Disclosures None.

References

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